ATTACHMENT E

510(k) SUMMARY

Trade Name: **BRM SWING-OFF SCREW**

Sponsor: **Advanced Interventional Technology LLC**
6703 NW 167 Street, Suite C-9
Miami, Fla 33015

Contact: E. March
GAMA Associates LLC
Ph- 240.506.3212
Email- edogama@comcast.net

Device Generic Name: **Bone Fixation Screw**

Classification: CFR 888.3040 Class II

Product Code: HWC

AUG 2 1 2013

Product Description

The BRM SWING OFF Screw is made of titanium alloy (Ti6Al4V- ELI) according to ISO 5832-3 and ASTM F 136. It is self-drilling and self-tapping and consists of a screw with a flat thin head which is integrated with a short round shaft. The shaft is fixed on a standard surgical shaft and separates from the screw when the head comes in contact with cortical bone.

The screw is available in two different diameters (2.0 and 2.7 mm) and in length from 10 to 15 mm for Ø 2.0 mm and from 10 to 17 mm for Ø 2.7 mm. The screws are anodized and color-coded (yellow) to be easily recognized. The head design facilitates maximum loading and compression. The self-drilling tip easily penetrates the cortical shell. A Swing-Off Terminal Screw Driver is offered for ease of use.

Indications for Use:

The AIT BRM SWING-OFF SCREW is indicated for surgical fixation of bone fractures, osteotomies and bone reconstruction in order to position and maintain bony fragments in a desired orientation and to provide stable fixation of the osteotomy site until a stable bony union occurs.
Examples include but are not limited to:

-Fixation of small bone fragments

Date Prepared: 21 Aug. 2013

-Weil osteotomy
-Mono-cortical fixation
-Osteotomies and fractures fixation in foot and hand

Predicate Devices
- Wright Medical Snap-off Screw (K050819)
- Z-Medical's Z-snap-off Screw (K121277)

Substantial Equivalence Information
Based on available 510k information including engineering analyses and insertion testing, AIT bone fixation (screw) devices are deemed substantially equivalent to the predicate devices in terms of indications for use, material, technology and design specifications.

Date Prepared: 21 Aug. 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2013

Advanced Interventional Technology LLC
% Mr. Eduardo March
GAMA Associates LLC
7000 Cashell Manor Court
Derwood, Maryland 20855

Re: K130627
Trade/Device Name: BRM Swing-Off Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 19, 2013
Received: July 22, 2013

Dear Mr. March:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130627

Device Name: BRM Swing-Off Screw

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Prescription Use __X___ AND / OR Over-the -Counter Use ____
(PART 21 CFR 801.Subpart D) (PART 21 CFR 801.Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, OFFICE OF DEVICE EVALUATION

Elizabeth L. Frank -S

Division of Orthopedic Devices